

improves overall DTB time and transfer time. In addition, it has the potential to decrease the frequency of false activations, therefore improving cost-efficiency of a network's STEMI system.

TCT-113

Focal Treatment of Lower Extremity Post-PTA Dissection Using The Tack-It Endovascular Staple Device: First-in-man Trial With One Year Follow-up

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Background: The purpose of this study was to evaluate the safety, feasibility, and results of using the Tack-It Endovascular Stapler™ to manage post-PTA dissection. Stents are used to manage of post-PTA dissection of the lower extremity arteries. This generally provides an acceptable post-intervention angiographic result but has long-term disadvantages such as in-stent restenosis and fracture. Focal treatment of post-PTA dissection and avoidance of stent placement in this setting is the function of the Tack-It device.

Methods: A total of 15 limbs (11 patients) with 25 lesion treatment sites were treated with the study device between December, 2009 and March, 2010. In the study group, 7 subjects had lesion treatments in one leg and 4 subjects had lesion treatments treated in bilateral extremities for lesions of the SFA, popliteal, or tibial arteries or a combination of these. Indications were CLI in 9 of the 15 limbs and claudication in 6.

Results: Acute technical success for luminal patency at the end of the study procedure was achieved with Tack placement and tissue apposition in 100% of all treated dissections. 50 Tacks were placed and placement was accurate in 96% (48/50). Tack placement successfully provided a smooth, post-angioplasty blood vessel surface and permanently secured post-PTA dissections. Mean procedure time was 51 minutes (range 10 – 128 minutes). Mean fluoroscopy time was 13 minutes (range 5 – 30 minutes). Two patients died and 2 were lost to follow-up during the year after the procedure. There were no device related complications. There were no major limb amputations. 18 of the 25 lesions were available for follow-up at one year. There was recurrent stenosis (>50%) in 3 of 18. One patient with gangrene and a popliteal occlusion returned with a recurrent stenosis at 3 months and required repeat angioplasty and Tack placement for a TLR rate of 4%. Overall angiographic patency at one year was 83.3%.

Conclusions: Use of the Tack-It Endovascular Stapler™ to manage post-PTA dissections is safe and feasible, and resulted in permanent securement of dissection flaps without stent placement and with reasonable angiographic patency at one-year.

TCT-114

Feasibility of Noninvasive Atherectomy: Plaque Ablation with Cavitation-Based Focused Ultrasound (Histotripsy)

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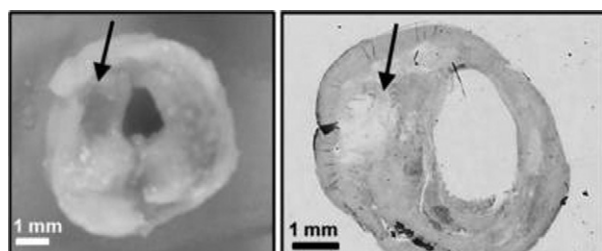
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Background: Histotripsy is a novel technique that uses high-amplitude focused ultrasound pulses to create cavitation in a targeted tissue, with resultant mechanical breakdown of the tissue structure. Ultrasound imaging provides feedback for the therapy, including targeting and monitoring treatment progression. We assessed the feasibility of histotripsy for ablating large vessel plaque.

Methods: Human plaque specimens obtained from carotid or femoral endarterectomy were fixed to a gelatin substrate and placed in a water tank. In 4 samples, the focus was scanned within the plaque to try to create a channel through it. In 3 samples, multiple fixed focal ablations were performed to evaluate erosion rate. Histological analysis was performed post treatment to examine ablation efficacy for different plaque types.

Results: Tissue breakdown was evident in most samples. Cavitation was observed by B-Mode imaging on the surface or within the plaque volume during treatment, indicating the region of disruption. Channels up to 1 cm were created within the bulk of the plaque. Ablation rate was strongly dependent on plaque type: fatty material could be ablated within a few seconds in the focus, while very fibrous material required ~5-15 minutes per focal volume. No damage was observed to calcific material. The figure shows gross morphology (left) and histology (right) of a channel created adjacent to the lumen in a fibrous-fatty plaque.

Conclusions: Histotripsy provides a noninvasive method of ablation of atherosclerotic plaque. We are currently exploring the feasibility of this technique for treatment of femoral-popliteal disease.



Endovascular Aortic Repair and Thoracic Endovascular Aortic Repair

Hall D

Tuesday, October 23, 2012, 8:00 AM–10:00 AM

Abstract nos: 115-132

TCT-115

Hybrid endovascular repair for aortic arch pathology: intermediate outcomes and complications

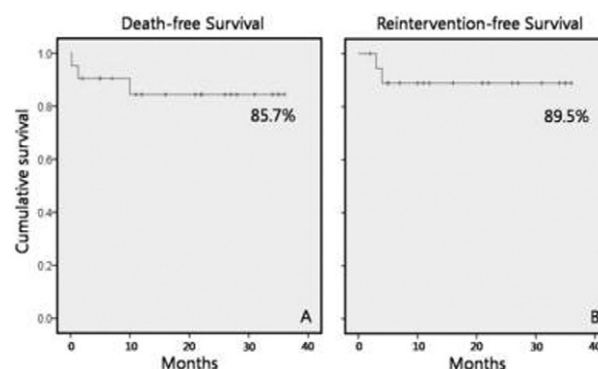
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Background: To evaluate the outcomes of hybrid endovascular repair for aortic arch pathology.

Methods: This study was a retrospective analysis involving patients who underwent hybrid endovascular repair for aortic arch pathologies.

Results: Twenty-one patients (16 men; mean age, 64.7±16.2 years) with aortic arch pathologies were treated by hybrid endovascular repair. The indications for treatment included increased aneurysm size in 16 cases (71.4%), rupture or impending aneurysmal rupture in 5 cases (23.8%), and rapid growth of aortic dissection (≥ 10mm/y) in 1 case (4.8%). Supra-aortic vessel transposition and stent-graft implantation were achieved in all cases. Two types of stent-graft was used, as follows: the Seal thoracic stent-graft in 14 patients (66.7%); and the Valiant stent grafts in 7 patients (33.3%). Peri-operative complications affected 5 patients (23.8%), as follows: bleeding (n=4, 19.0%); stroke (n=3, 14.3%); renal failure (n=2, 9.5%); vascular injury (n=1, 4.8%), and respiratory failure (n=1, 4.8%). Two patients died within 30 days (9.5%). Technical success was achieved in 15 patients (71.5%). Early endoleaks were noted in 4 patients (19.0%). One patient died during follow-up (mean, 21.3±11.6 months) due to a de novo aortic dissection. Persistent early endoleaks were noted in 4 patients (19.0%); 2 of the 4 patients were successfully managed with implantation of additional stent-grafts. No late onset endoleaks were noted.



Conclusions: Hybrid treatment with supra-aortic vessel transposition and endovascular repair may be an option in frail patients in who open procedures is too risky.

TCT-116

A New Concept Of Stent: The Multilayer Flow Modulator. First Human Study In Thoraco Abdominal And Abdominal Aortic Aneurysms.

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Background: Thoraco Abdominal Aortic Aneurysms (TAAA) and Abdominal Aortic Aneurysms (AAA) are traditionally treated surgically, but more and more by interventional procedures (endografts, fenestrated grafts) with a high technical success rate but high complications rate (mortality 9-12%, endoleaks 10-20%, branch occlusion 3-11%, neurological complications 5-11%). We developed a new concept of stent, the Multilayer